CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

209184Orig1s000

PROPRIETARY NAME REVIEW(S)

PROPRIETARY NAME REVIEW

Division of Medication Error Prevention and Analysis (DMEPA)
Office of Medication Error Prevention and Risk Management (OMEPRM)
Office of Surveillance and Epidemiology (OSE)
Center for Drug Evaluation and Research (CDER)

***** This document contains proprietary information that cannot be released to the public*****

Date of This Review:	March 5, 2018
Application Type and Number:	NDA 209184
Product Name and Strength:	Inbrija (levodopa) inhalation powder 42 mg
Product Type:	Single ingredient combination product
Rx or OTC:	Rx
Applicant/Sponsor Name:	Acorda Therapeutics, Inc.
Panorama #:	2017-19475142
DMEPA Safety Evaluator:	Chad Morris, PharmD, MPH
DMEPA Team Leader:	Lolita White, PharmD

Contents

1 INTRODUCTION 1
1.1 Regulatory History 1
1.2 Product Information 1
2 RESULTS 1
2.1 Misbranding Assessment 1
2.2 Safety Assessment 2
3 CONCLUSIONS 5
3.1 Comments to the Applicant 5
4 REFERENCES 7
APPENDICES 7

1 INTRODUCTION

This review evaluates the proposed proprietary name, Inbrija, from a safety and misbranding perspective. The sources and methods used to evaluate the proposed name are outlined in the reference section and Appendix A respectively. The Applicant submitted an external name study, conducted by (b) (4), for this product.

1.1 REGULATORY HISTORY

The Applicant previously submitted the proposed proprietary name, (b) (4) (b) (4) However, the Division of Medication Error Prevention and Analysis (DMEPA) found the (b) (4)

Thus, the Applicant submitted the name, Inbrija, for review on August 10, 2016 and amended the submission to clarify the intended pronunciation on August 18, 2016. The proposed proprietary name, Inbrija, was found conditionally acceptable under IND 115750 on February 1, 2017. NDA 209184 was submitted on June 27, 2017 with the proprietary name request; however, the NDA received a RTF on August 25, 2017 so the name was not reviewed. The NDA was resubmitted on December 5, 2017

Consequently, Acorda resubmitted the proposed proprietary name, Inbrija, the with their resubmission after RTF. (b) (4) Acorda now proposes (b) (4) (b) (4) strength, 42 mg, for NDA 209184. All other product characteristics remain the same.

1.2 PRODUCT INFORMATION

The following product information is provided in the December 5, 2017 proprietary name submission.

- Intended Pronunciation: in-BRIH-jah
- Active Ingredient: levodopa
- Indication of Use: Intermittent treatment of symptoms of OFF periods in Parkinson's disease as an adjunct to a daily oral carbidopa and levodopa regimen
- Route of Administration: Oral inhalation using a breath-actuated inhaler device
- Dosage Form: inhalation powder
- Strength: 42 mg
- Dose and Frequency: Two 42 mg levodopa capsules (84 mg) given sequentially via oral inhalation using the inhaler device. The frequency of administration can be up to 5 times per day as needed to treat OFF symptoms during waking hours. The maximum daily dose is (b) (4) mg levodopa.
- How Supplied: The capsules are packaged in a foil-foil blister.
- (b) (4)

- Reference Listed Drug: Sinemet, NDA 17555

2 RESULTS

The following sections provide information obtained and considered in the overall evaluation of the proposed proprietary name.

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that the proposed name would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis (DMEPA) and the Division of Neurology Products (DNP) concurred with the findings of OPDP's assessment of the proposed name.

2.2 SAFETY ASSESSMENT

The following aspects were considered in the safety evaluation of the name.

2.2.1 United States Adopted Names (USAN) Search

There is no USAN stem present in the proprietary name[a].

2.2.2 Components of the Proposed Proprietary Name

The Applicant did not provide a derivation or intended meaning for the proposed name, Inbrija, in their submission. This proprietary name is comprised of a single word that does not contain any components (i.e. a modifier, route of administration, dosage form, etc.) that are misleading or can contribute to medication error.

2.2.3 Comments from Other Review Disciplines at Initial Review

In response to the OSE, December 22, 2017 e-mail, DNP did not forward any comments or concerns relating to the proposed proprietary name at the initial phase of the review.

2.2.4 FDA Name Simulation Studies

103 practitioners participated in DMEPA's prescription studies. Appendix B contains the results from the verbal and written prescription studies.

One participant in the outpatient study provided a supplemental comment that the proposed name "can be easily misinterpreted as Inbrya, especially if the dots above the "i" and "j" are missing." We considered the risk of confusion for the name pair, Inbrija and Inbrya, in Appendix C. We searched commonly used drug databases for the name, Inbrya, and did not obtain any direct hits or close hits for any existing products or products in development by that name. Therefore, we have no concerns of name confusion of Inbrija and Inbrya.

[a] USAN stem search conducted on February 2, 2018.

2.2.5 Phonetic and Orthographic Computer Analysis (POCA) Search Results

Our POCA search[b] identified 98 names with a combined phonetic and orthographic score of ≥55% or an individual phonetic or orthographic score ≥70%**.** These names are included in Table 1 below.

2.2.6 Names with Strength Overlap and Potential Orthographic, Spelling, and Phonetic Similarities

The proposed product, Inbrija will be available in 42 mg strength(s). Since this is not a typical strength that is commonly marketed, we searched the Electronic Drug Registration and Listing System (eDRLS) database to identify names with strength overlap. Names with strength overlap and potential orthographic, spelling, and phonetic similarities with proposed name that were not identified in POCA include Ipratropium. This name is included in Table 1A below. The names identified in the eDRLS database that are not likely to be confused due to notable spelling, orthographic and phonetic differences are listed in Appendix I.

Table 1A. eDRLS Search Results[c]	**POCA Score (%)**
Ipratropium bromide	32

2.2.7 Names Retrieved for Review Organized by Name Pair Similarity

Table 1 lists the number of names retrieved from our POCA search, eDRLS, FDA Prescription Simulation Study, and the (b) (4) external study. These name pairs are organized as highly similar, moderately similar or low similarity for further evaluation.

Table 1. Similarity Category	**Number of Names**
Highly similar name pair: combined match percentage score ≥70%	5
Moderately similar name pair: combined match percentage score ≥55% to ≤ 69%	93
Low similarity name pair: combined match percentage score ≤54%	48

[b] POCA search conducted on February 5, 2018 in version 4.2

[c] eDRLS search conducted on September 22, 2016.

2.2.8 Safety Analysis of Names with Potential Orthographic, Spelling, and Phonetic Similarities

Our analysis of the 146 names contained in Table 1 determined none of the names will pose a risk for confusion as described in Appendices C through H.

2.2.9 Communication of DMEPA's Analysis at Midpoint of Review

DMEPA communicated our findings to DNP via e-mail on March 2, 2018. At that time, we also requested additional information or concerns that could inform our review. Per e-mail correspondence from DNP on March 2, 2018, they stated no additional concerns with the proposed proprietary name, Inbrija.

3 CONCLUSIONS

The proposed proprietary name is acceptable.

If you have any questions or need clarifications, please contact Ruth Maduro, OSE project manager, at 240-402-4232.

3.1 COMMENTS TO THE APPLICANT

We have completed our review of the proposed proprietary name, Inbrija, and have concluded that this name is acceptable.

If any of the proposed product characteristics as stated in your December 5, 2017 submission are altered prior to approval of the marketing application, the name must be resubmitted for review.

4 REFERENCES

1. ***USAN Stems (http://www.ama-assn.org/ama/pub/physician-resources/medical-science/united-states-adopted-names-council/naming-guidelines/approved-stems.page)***

   USAN Stems List contains all the recognized USAN stems.

2. ***Phonetic and Orthographic Computer Analysis (POCA)***

POCA is a system that FDA designed. As part of the name similarity assessment, POCA is used to evaluate proposed names via a phonetic and orthographic algorithm. The proposed proprietary name is converted into its phonemic representation before it runs through the phonetic algorithm. Likewise, an orthographic algorithm exists that operates in a similar fashion. POCA is publicly accessible.

Drugs@FDA

Drugs@FDA is an FDA Web site that contains most of the drug products approved in the United States since 1939. The majority of labels, approval letters, reviews, and other information are available for drug products approved from 1998 to the present. Drugs@FDA contains official information about FDA-approved *brand name* and *generic drugs*; *therapeutic biological products*, *prescription* and *over-the-counter* human drugs; and *discontinued drugs* (see Drugs @ FDA Glossary of Terms, available at http://www.fda.gov/Drugs/InformationOnDrugs/ucm079436.htm#ther_biological).

RxNorm

RxNorm contains the names of prescription and many OTC drugs available in the United States. RxNorm includes generic and branded:

- Clinical drugs – pharmaceutical products given to (or taken by) a patient with therapeutic or diagnostic intent
- Drug packs – packs that contain multiple drugs, or drugs designed to be administered in a specified sequence

Radiopharmaceuticals, contrast media, food, dietary supplements, and medical devices, such as bandages and crutches, are all out of scope for RxNorm (http://www.nlm.nih.gov/research/umls/rxnorm/overview.html#).

Division of Medication Errors Prevention and Analysis proprietary name consultation requests

This is a list of proposed and pending names that is generated by the Division of Medication Error Prevention and Analysis from the Access database/tracking system.

3. ***Electronic Drug Registration and Listing System (eDRLS) database***

The electronic Drug Registration and Listing System (eDRLS) was established to supports the FDA's Center for Drug Evaluation and Research (CDER) goal to establish a common Structured Product Labeling (SPL) repository for all facilities that manufacture regulated drugs. The system is a reliable, up-to-date inventory of FDA-regulated, drugs and establishments that produce drugs and their associated information.

APPENDICES

Appendix A

FDA's Proprietary Name Risk Assessment evaluates proposed proprietary names for misbranding and safety concerns.

1. **Misbranding Assessment**: For prescription drug products, OPDP assesses the name for misbranding concerns. For over-the-counter (OTC) drug products, the misbranding assessment of the proposed name is conducted by DNDP. OPDP or DNDP evaluates proposed proprietary names to determine if the name is false or misleading, such as by making misrepresentations with respect to safety or efficacy. For example, a fanciful proprietary name may misbrand a product by suggesting that it has some unique effectiveness or composition when it does not (21 CFR 201.10(c)(3)). OPDP or DNDP provides their opinion to DMEPA for consideration in the overall acceptability of the proposed proprietary name.
2. **Safety Assessment**: The safety assessment is conducted by DMEPA, and includes the following:

a. Preliminary Assessment: We consider inclusion of USAN stems or other characteristics that when incorporated into a proprietary name may cause or contribute to medication errors (i.e., dosing interval, dosage form/route of administration, medical or product name abbreviations, names that include or suggest the composition of the drug product, etc.) See prescreening checklist below in Table 2*. DMEPA defines a medication error as any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. [d]

[d] National Coordinating Council for Medication Error Reporting and Prevention. http://www nccmerp.org/aboutMedErrors html. Last accessed 10/11/2007.

***Table 2- Prescreening Checklist for Proposed Proprietary Name**

	Answer the questions in the checklist below. Affirmative answers to any of these questions indicate a potential area of concern that should be carefully evaluated as described in this guidance.
Y/N	**Is the proposed name obviously similar in spelling and pronunciation to other names?**
	Proprietary names should not be similar in spelling or pronunciation to proprietary names, established names, or ingredients of other products.
Y/N	**Are there inert or inactive ingredients referenced in the proprietary name?**
	Proprietary names should not incorporate any reference to an inert or inactive ingredient in a way that might create an impression that the ingredient's value is greater than its true functional role in the formulation (21 CFR 201.10(c)(4)).
Y/N	**Does the proprietary name include combinations of active ingredients?**
	Proprietary names of fixed combination drug products should not include or suggest the name of one or more, but not all, of its active ingredients (see 21 CFR 201.6(b)).
Y/N	**Is there a United States Adopted Name (USAN) stem in the proprietary name?**
	Proprietary names should not incorporate a USAN stem in the position that USAN designates for the stem.
Y/N	**Is this proprietary name used for another product that does not share at least one common active ingredient?**
	Drug products that do not contain at least one common active ingredient should not use the same (root) proprietary name.
Y/N	**Is this a proprietary name of a discontinued product?**
	Proprietary names should not use the proprietary name of a discontinued product if that discontinued drug product does not contain the same active ingredients.

b. Phonetic and Orthographic Computer Analysis (POCA): Following the preliminary screening of the proposed proprietary name, DMEPA staff evaluates the proposed name against potentially similar names. In order to identify names with potential similarity to the proposed proprietary name, DMEPA enters the proposed proprietary name in POCA and queries the name against the following drug reference databases, Drugs@fda, CernerRxNorm, and names in the review pipeline using a 55% threshold in POCA. DMEPA reviews the combined orthographic and phonetic matches and group the names into one of the following three categories:

- Highly similar pair: combined match percentage score ≥70%.
- Moderately similar pair: combined match percentage score ≥55% to ≤ 69%.
- Low similarity: combined match percentage score ≤54%.

Using the criteria outlined in the check list (Table 3-5) that corresponds to each of the three categories (highly similar pair, moderately similar pair, and low similarity), DMEPA evaluates the name pairs to determine the acceptability or non-acceptability of a proposed proprietary name. The intent of these checklists is to increase the transparency and predictability of the safety determination of whether a proposed name is vulnerable to confusion from a look-alike or sound-alike perspective. Each bullet below corresponds to the name similarity category cross-references the respective table that addresses criteria that DMEPA uses to determine whether a name presents a safety concern from a look-alike or sound-alike perspective.

- For highly similar names, differences in product characteristics often cannot mitigate the risk of a medication error, including product differences such as strength and dose. Thus, proposed proprietary names that have a combined score of ≥ 70 percent are at risk for a look-alike sound-alike confusion which is an area of concern (See Table 3).
- Moderately similar names are further evaluated to identify the presence of attributes that are known to cause name confusion.
    - Name attributes: We note that the beginning of the drug name plays a significant role in contributing to confusion. Additionally, drug name pairs that start with the same first letter and contain a shared letter string of at least 3 letters in both names are major contributing factor in the confusion of drug names[e]. We evaluate all moderately similar names retrieved from POCA to identify the above attributes. These names are further evaluated to identify overlapping or similar strengths or doses.
    - Product attributes: Moderately similar names of products that have overlapping or similar strengths or doses represent an area for concern for FDA. The dose and strength information is often located in close proximity to the drug name itself on prescriptions and medication orders, and the information can be an important factor that either increases or decreases the potential for confusion between similarly named drug pairs. The ability of other product characteristics to mitigate confusion (e.g.,

[e] Shah, M, Merchant, L, Characteristics That May Help in the Identification of Potentially Confusing Proprietary Drug Names. Therapeutic Innovation & Regulatory Science, September 2016

route, frequency, dosage form) may be limited when the strength or dose overlaps. DMEPA reviews such names further, to determine whether sufficient differences exist to prevent confusion. (See Table 4).

- Names with low similarity that have no overlap or similarity in strength and dose are generally acceptable (See Table 5) unless there are data to suggest that the name might be vulnerable to confusion (e.g., prescription simulation study suggests that the name is likely to be misinterpreted as a marketed product). In these instances, we would reassign a low similarity name to the moderate similarity category and review according to the moderately similar name pair checklist.

c. FDA Prescription Simulation Studies: DMEPA staff also conducts a prescription simulation studies using FDA health care professionals.

Three separate studies are conducted within the Centers of the FDA for the proposed proprietary name to determine the degree of confusion of the proposed proprietary name with marketed U.S. drug names (proprietary and established) due to similarity in visual appearance with handwritten prescriptions or verbal pronunciation of the drug name. The studies employ healthcare professionals (pharmacists, physicians, and nurses), and attempts to simulate the prescription ordering process. The primary Safety Evaluator uses the results to identify orthographic or phonetic vulnerability of the proposed name to be misinterpreted by healthcare practitioners.

In order to evaluate the potential for misinterpretation of the proposed proprietary name in handwriting and verbal communication of the name, inpatient medication orders and/or outpatient prescriptions are written, each consisting of a combination of marketed and unapproved drug products, including the proposed name. These orders are optically scanned and one prescription is delivered to a random sample of participating health professionals via e-mail. In addition, a verbal prescription is recorded on voice mail. The voice mail messages are then sent to a random sample of the participating health professionals for their interpretations and review. After receiving either the written or verbal prescription orders, the participants record their interpretations of the orders which are recorded electronically.

d. Comments from Other Review Disciplines: DMEPA requests the Office of New Drugs (OND) and/or Office of Generic Drugs (OGD), ONDQA or OBP for their comments or concerns with the proposed proprietary name, ask for any clinical issues that may impact the DMEPA review during the initial phase of the name review. Additionally, when applicable, at the same time DMEPA requests concurrence/non-concurrence with OPDP's decision on the name. The primary Safety Evaluator addresses any comments or concerns in the safety evaluator's assessment.

   The OND/OGD Regulatory Division is contacted a second time following our analysis of the proposed proprietary name. At this point, DMEPA conveys their decision to accept or reject the name. The OND or OGD Regulatory Division is requested to provide any further information that might inform DMEPA's final decision on the proposed name.

   Additionally, other review disciplines opinions such as ONDQA or OBP may be considered depending on the proposed proprietary name.

   When provided, DMEPA considers external proprietary name studies conducted by or for the Applicant/Sponsor and incorporates the findings of these studies into the overall risk assessment.

The DMEPA primary reviewer assigned to evaluate the proposed proprietary name is responsible for considering the collective findings, and provides an overall risk assessment of the proposed proprietary name.

Table 3. Highly Similar Name Pair Checklist (i.e., combined Orthographic and Phonetic score is ≥ 70%).

Answer the questions in the checklist below. Affirmative answers to some of these questions suggest that the pattern of orthographic or phonetic differences in the names may render the names less likely to confusion, provided that the pair does not share a common strength or dose.			
Orthographic Checklist		Phonetic Checklist	
Y/N	Do the names begin with different first letters? *Note that even when names begin with different first letters, certain letters may be confused with each other when scripted.*	**Y/N**	Do the names have different number of syllables?
Y/N	Are the lengths of the names dissimilar* when scripted? **FDA considers the length of names different if the names differ by two or more letters.*	**Y/N**	Do the names have different syllabic stresses?
Y/N	Considering variations in scripting of some letters (such as *z* and *f*), is there a different number or placement of upstroke/downstroke letters present in the names?	**Y/N**	Do the syllables have different phonologic processes, such vowel reduction, assimilation, or deletion?

Y/N	Is there different number or placement of cross-stroke or dotted letters present in the names?	Y/N	Across a range of dialects, are the names consistently pronounced differently?
Y/N	Do the infixes of the name appear dissimilar when scripted?		
Y/N	Do the suffixes of the names appear dissimilar when scripted?		

Table 4: Moderately Similar Name Pair Checklist (i.e., combined score is ≥55% to ≤69%).

Step 1	Review the DOSAGE AND ADMINISTRATION and HOW SUPPLIED/STORAGE AND HANDLING sections of the prescribing information (or for OTC drugs refer to the Drug Facts label) to determine if strengths and doses of the name pair overlap or are very similar. Different strengths and doses for products whose names are moderately similar may decrease the risk of confusion between the moderately similar name pairs. Name pairs that have overlapping or similar strengths or doses have a higher potential for confusion and should be evaluated further (see Step 2). Because the strength or dose could be used to express an order or prescription for a particular drug product, overlap in one or both of these components would be reason for further evaluation. For single strength products, also consider circumstances where the strength may not be expressed. For any i.e. drug products comprised of more than one active ingredient, consider whether the strength or dose may be expressed using only one of the components. To determine whether the strengths or doses are similar to your proposed product, consider the following list of factors that may increase confusion: • Alternative expressions of dose: 5 mL may be listed in the prescribing information, but the dose may be expressed in metric weight (e.g., 500 mg) or in non-metric units (e.g., 1 tsp, 1 tablet/capsule). Similarly, a strength or dose of 1000 mg may be expressed, in practice, as 1 g, or vice versa. • Trailing or deleting zeros: 10 mg is similar in appearance to 100 mg which may potentiate confusion between a name pair with moderate similarity. • Similar sounding doses: 15 mg is similar in sound to 50 mg

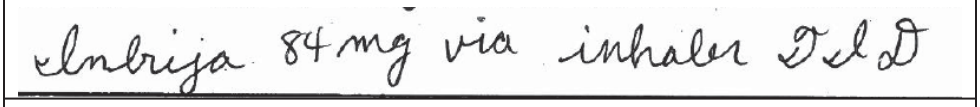
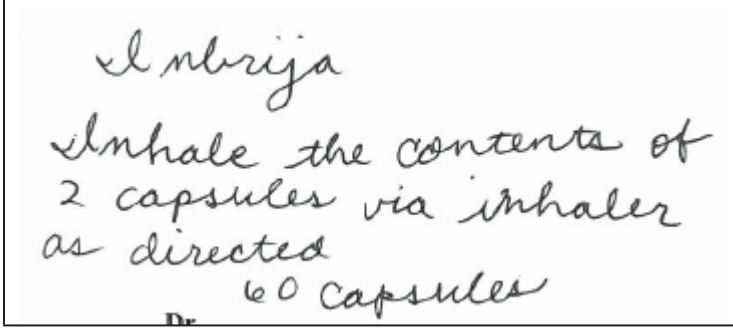
Step 2	Answer the questions in the checklist below. Affirmative answers to some of these questions suggest that the pattern of orthographic or phonetic differences in the names may reduce the likelihood of confusion for moderately similar names **with** overlapping or similar strengths or doses.	
	Orthographic Checklist (Y/N to each question) • Do the names begin with different first letters? Note that even when names begin with different first letters, certain letters may be confused with each other when scripted. • Are the lengths of the names dissimilar* when scripted? *FDA considers the length of names different if the names differ by two or more letters. • Considering variations in scripting of some letters (such as *z* and *f*), is there a different number or placement of upstroke/downstroke letters present in the names? • Is there different number or placement of cross-stroke or dotted letters present in the names? • Do the infixes of the name appear dissimilar when scripted? • Do the suffixes of the names appear dissimilar when scripted?	Phonetic Checklist (Y/N to each question) • Do the names have different number of syllables? • Do the names have different syllabic stresses? • Do the syllables have different phonologic processes, such vowel reduction, assimilation, or deletion? • Across a range of dialects, are the names consistently pronounced differently?

Table 5: Low Similarity Name Pair Checklist (i.e., combined score is ≤54%).

Names with low similarity are generally acceptable unless there are data to suggest that the name might be vulnerable to confusion (e.g., prescription simulation study suggests that the name is likely to be misinterpreted as a marketed product). In these instances, we would reassign a low similarity name to the moderate similarity category and review according to the moderately similar name pair checklist.

Appendix B: Prescription Simulation Samples and Results

Figure 1. Inbrija Study (Conducted on January 3, 2018)

Handwritten Medication Order/Prescription	Verbal Prescription
Medication Order:  Outpatient Prescription: 	Inbrija Inhale the contents of 2 capsules via inhaler as directed. #60 capsules

FDA Prescription Simulation Responses (Aggregate 2 Rx Study Report)

Study Name: Inbrija
As of Date 2/2/2018

293 People Received Study
103 People Responded

Study Name: Inbrija

OUTPATIENT	VOICE	INPATIENT
INBRIJA (30)	ENBREGIA (1)	IMBIJA (1)
INBRIYA (1)	ENBREJA (2)	IMBRIJA (2)
INBRIZA (1)	ENBRIGA (3)	INBRIGA (1)
INBRYA (2)	ENBRIJA (2)	INBRIJA (32)
INBRYIJA (1)	IMBREJA (1)	INLRIJA (2)
INJRIJA (1)	INBREEJA (1)	
INLIRIJA (1)	INBREGIA (8)	
INLRIJA (1)	INBREJA (5)	
	INBRIGA (1)	
	INBRIJA (3)	

Appendix C: Highly Similar Names (e.g., combined POCA score is ≥70%)

No.	**Proposed name: Inbrija** **Established name: levodopa** **Dosage form: inhalation powder** **Strength(s): 42 mg** **Usual Dose: 84 mg (2 cap) inhaled up to 5xd**	**POCA Score (%)**	**Orthographic and/or phonetic differences in the names sufficient to prevent confusion** **Other prevention of failure mode expected to minimize the risk of confusion between these two names.**
1.	Inbrija	100	This is the name under consideration
2.	Inbrya	78	Name identified in FDA Prescription Simulation study. Unable to find product characteristics in commonly used drug databases.
3.	Inbrin	78	Orthographic: Inbrija has a downstroke letter (‘j’) in the 5th position. Phonetic: Inbrija has three syllables and Inbrin has two syllables. Name identified in external study. Unable to find product characteristics in commonly used drug databases.
4.	Zinbryta	76	Orthographic: The prefixes of this name pair have sufficient orthographic differences (‘In’ vs. ‘Zin’). Inbrija does not have any cross-stroke letters, whereas Zinbryta has a cross-stroke letter (‘t’) in the 7th position. Phonetic: The first and third syllables of this name pair sound different (‘In’ vs. ‘Zin’ and ‘jah’ vs. ‘ta’). There is no overlap in product strength or dose. Inbrija is available in the following strength: 42 mg with a dose of 84 mg per dose given via inhaler. Zinbryta is available in the following strength: 150 mg with a dose of 150 mg administered subcutaneously.
5.	Simbrinza	70	Orthographic: The prefixes (‘In’ vs ‘Sim’) of this name pair have sufficient orthographic differences. Phonetic: The first (‘in’ vs ‘sim’) and second (‘bree’ vs ’brin’) syllables of this name pair sound different. Product Characteristics: There is no overlap in product strength or dose. Inbrija is available in a 42 mg strength with a dose of 84 mg (2 capsules) per dose given via inhaler. Simbrinza is available in 1%/0.2% strength with a dose of 1 drop administered ophthalmically.

Appendix D: Moderately Similar Names (e.g., combined POCA score is ≥55% to ≤69%) with no overlap or numerical similarity in Strength and/or Dose

No.	Name	POCA Score (%)
6.	(b) (4)***	65
7.	(b) (4)***	63
8.	Innopran	62
9.	(b) (4)***	61
10.	Ibrance	60
11.	Ibuprin	60
12.	(b) (4)***	60
13.	Intrarosa	59
14.	Dendrid	58
15.	Inspra	58
16.	(b) (4)***	58
17.	Inderide	57
18.	Inderide-40/25	57
19.	Inderide-80/25	57
20.	Ibren	56
21.	Inlyta	50

Appendix E: Moderately Similar Names (e.g., combined POCA score is ≥55% to ≤69%) with overlap or numerical similarity in Strength and/or Dose

No.	**Proposed name: Inbrija Established name: levodopa Dosage form: inhalation powder Strength(s): 42 mg Usual Dose: 84 mg (2 cap) inhaled up to 5xd**	POCA Score (%)	**Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
22.	Intron A	69	This name pair has sufficient orthographic and phonetic differences.
23.	(b) (4)***	68	This name pair has sufficient orthographic and phonetic differences.
24.	(b) (4)***	65	This name pair has sufficient orthographic and phonetic differences.
25.	Alunbrig	64	This name pair has sufficient orthographic and phonetic differences.
26.	Imbruvica	64	This name pair has sufficient orthographic and phonetic differences.
27.	Inderal La	64	This name pair has sufficient orthographic and phonetic differences.

No.	Proposed name: Inbrija Established name: levodopa Dosage form: inhalation powder Strength(s): 42 mg Usual Dose: 84 mg (2 cap) inhaled up to 5xd	POCA Score (%)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
28.	Inderal-La	64	This name pair has sufficient orthographic and phonetic differences.
29.	Emtriva	62	This name pair has sufficient orthographic and phonetic differences.
30.	Fibryga	62	This name pair has sufficient orthographic and phonetic differences. The following differences in product characteristics also minimize the potential for error: Dosage form: injection vs. powder for injection Route of administration: subcutaneous vs intravenous Strength: 42 mg vs 1 g Dose and Frequency: 84 mg (2 caps) up to 5 times daily vs individualized dosage based on plasma fibrinogen concentration and body weight
31.	Penbritin	62	This name pair has sufficient orthographic and phonetic differences.
32.	Inderal	60	This name pair has sufficient orthographic and phonetic differences.
33.	Ingrezza	60	This name pair has sufficient orthographic and phonetic differences.
34.	Intropin	60	This name pair has sufficient orthographic and phonetic differences.
35.	(b) (4)***	60	This name pair has sufficient orthographic and phonetic differences.
36.	Invirase	58	This name pair has sufficient orthographic and phonetic differences.
37.	Enbrel	57	This name pair has sufficient orthographic and phonetic differences.
38.	Inamrinone	56	This name pair has sufficient orthographic and phonetic differences.
39.	Invega	56	This name pair has sufficient orthographic and phonetic differences.
40.	(b) (4)***	55	This name pair has sufficient orthographic and phonetic differences.
41.	Introvale	55	This name pair has sufficient orthographic and phonetic differences.
42.	Libritabs	55	This name pair has sufficient orthographic and phonetic differences.

No.	Proposed name: Inbrija Established name: levodopa Dosage form: inhalation powder Strength(s): 42 mg Usual Dose: 84 mg (2 cap) inhaled up to 5xd	POCA Score (%)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
43.	Penbritin-S	55	This name pair has sufficient orthographic and phonetic differences.
44.	Binora	50	This name pair has sufficient orthographic and phonetic differences.

Appendix F: Low Similarity Names (e.g., combined POCA score is ≤54%)

No.	Name	POCA Score (%)
45.	Andro La	46
46.	Andro La 200	46
47.	Arqeva	34
48.	Ed Bron G	49
49.	Egrifta	48
50.	Embeda	48
51.	Emerita	50
52.	Endrate	54
53.	Endur-Acin	54
54.	Enduron	46
55.	End-Zit	47
56.	Enjuvia	51
57.	Enpresse-21	46
58.	Enpresse-28	46
59.	Entereg	46
60.	Enterocina	52
61.	Entre-B	52
62.	Entre-S	48
63.	Entrocel	46
64.	Genpril	52
65.	Imidurea	52
66.	Incruse	52
67.	indibulin	50
68.	Indigo	54
69.	indiplon	43
70.	Indocid	50
71.	indriline	57
72.	Infanrix	54
73.	ingliforib	46

No.	Name	POCA Score (%)
74.	Inocor I. V.	54
75.	Integra F	54
76.	Introl	52
77.	Invarest	54
78.	Iprivask	52
79.	Lemtrada	51
80.	Limbrel	54
81.	Nostrilla	52
82.	Pimtrea	49
83.	Spiriva	54
84.	Ipratroprium Bromide	32

Appendix G: Names not likely to be confused or not used in usual practice settings for the reasons described**.**

No.	Name	POCA Score (%)	Failure preventions
85.	(b) (4)***	62	Proposed proprietary name withdrawn by the Applicant. Product approved under new proprietary name, Bridion.
86.	(b) (4)***	63	Proposed name for IND 126779 found unacceptable by DMEPA (Panorama # 2017-13946987). Subsequently, the applicant submitted the proposed name (b) (4)*** to NDA 209355.
87.	Fibryna	62	Name identified in Names Entered by Safety Evaluator database. Unable to find product characteristics in internal databases.
88.	Ibrin	64	Brand discontinued with no generic equivalent available. NDA 017879 withdrawn FR effective 09/04/1991.
89.	Imbrilon	65	International product formerly marketed in Europe and Hong Kong.
90.	Imigran	56	International product marketed in Africa, Asia, Australia, Europe, and Mexico.
91.	Incurin	59	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
92.	Inderide La	60	Brand discontinued with no generic equivalent available.
93.	Inderide La 120/50	60	Brand discontinued with no generic equivalent available.
94.	Inderide La 160/50	60	Brand discontinued with no generic equivalent available.
95.	Inderide La 80/50	60	Brand discontinued with no generic equivalent available.
96.	Indoramin	58	International product formerly marketed in Europe.
97.	Nobrium	55	International product marketed in the UK.
98.	Sandrena	62	International product marketed in Australia, Chile, Italy, Mexico, United Kingdom, and Brazil.

No.	Name	POCA Score (%)	Failure preventions
99.	Vinbarbital	61	Name identified in external study. Unable to find product characteristics in commonly used drug databases.

Appendix H: Names not likely to be confused due to absence of attributes that are known to cause name confusion[f].

No.	Name	POCA Score (%)
100.	Abreva	56
101.	Absorica	58
102.	Adprin B	60
103.	Amprid	56
104.	Android	62
105.	Android 10	62
106.	Android 25	62
107.	Android 5	62
108.	Android-10	62
109.	Android-25	62
110.	Android-F	56
111.	Anefrin	56
112.	Binocrit	56
113.	Condrin	56
114.	Diprivan	59
115.	Empirin	56
116.	Enaprilat	58
117.	Endari	55
118.	Enriav	56
119.	Enrubi	58
120.	Entaprin	56
121.	Genprin	57
122.	Migran-A	56
123.	Miniprin	60
124.	Minitran	58
125.	Moderiba	56
126.	Natroba	56
127.	Omidria	57

[f] Shah, M, Merchant, L, Chan, I, and Taylor, K. Characteristics That May Help in the Identification of Potentially Confusing Proprietary Drug Names. Therapeutic Innovation & Regulatory Science, September 2016

No.	Name	POCA Score (%)
128.	Rice Bran	56
129.	Sandril	56
130.	Simparica	58
131.	Spinraza	58
132.	Synadrin	56
133.	Tanabid Da	58
134.	Uniparin	56
135.	Vimbray	58
136.	Yenrila	57
137.	Zincfrin	56
138.	Zinplava	56

Appendix I: Names identified in the eDRLS database not likely to be confused due to notable spelling, orthographic and phonetic differences.

No.	Name
139.	Atrovent
140.	B4
141.	Beconase
142.	Healthy Hands
143.	Hydrating Instant Hand Sanitizer
144.	Hydrophor
145.	Knockout
146.	Welmedix HomeCare PRO Fragile Skin Protectant

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/s/

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03/05/2018

LOLITA G WHITE
03/05/2018